Remarks

Claims 15-20 are currently pending in the application. Claim 15 has been amended to more particularly point out that the uncoated sealing section and an edge region of the inert film flatly abut in the working position against the syringe or carpule cylinder and that an annular continuous sealing zone is directly adjacent to and directly adjoins the edge region of the inert film enveloping the piston section and abuts against the inside wall of the syringe or carpule cylinder. Further, claim 15 has been amended to more particularly point out that the annular continuous sealing zone is aligned with a surface of the edge region of the inert film or projects slightly radially beyond the surface, so that in the working position the piston stopper abuts with the sealing section fully against the syringe or carpule cylinder.

Claim 16 has been amended to conform to amended claim 15, to overcome the formal objections and the rejection and to more particularly point out that the sealing zone is provided as a straight extension to the surface of the edge region of the inert film that in the working position abuts against the syringe or carpule cylinder or slightly projects radially beyond surface of the edge of the inert film.

Currently amended claims 15 and 16 are at least supported by Figs. 9-12 and specification paragraph [0012], [0043] and [0044]. Accordingly, no new matter has been added and entry of the amendments is respectfully requested.

Claim Objections

The Examiner objected to claim 16 because of several informalities. Specifically, the Examiner asserted that the phrases "the outer circumferential edge of the inert film" in lines 2-3 and "the outer circumferential edge" in line 4 lack antecedent basis. In view of the Examiner's comments, Applicant has amended claim 16 to delete the above-identified phrases and add the phrase "the surface of the edge of the inert film". Proper antecedent basis for this phrase can be found in amended claim 15, from which amended claim 16 depends. Therefore, the objection to claim 16 is moot and Applicant respectfully submits that claim 16 is in full compliance with the requirements. Applicant respectfully requests that the objection to claim 16 be withdrawn.

Claim Rejections - 35 U.S.C. § 112

The Examiner rejected claim 16 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner asserted that it is unclear which outer circumferential edge is being referred to in line 4. Further, the Examiner asserted that, in the case that it is the outer or outermost circumferential edge of the inert film, it is unclear how the sealing zone can slightly project beyond the circumferential edge of the inert film when it has already been established that the sealing zone forms a plane with the entire outer circumferential edge of the inert film.

In view of the Examiner's comments, Applicant has amended claim 16 to delete the recitation to the "outer circumferential edge of the inert film" and add the phrase "the surface of the edge of the inert film" as is described above. Further, Applicant has amended claim 15 to delete the recitation that "the continuous sealing zone forms a plane with . . . an entire outermost circumferential edge of the inert film" and add the phrase "said annular continuous sealing zone (13) being aligned with a surface of the edge region of the inert film (9') or projecting slightly radially beyond the surface". Therefore, the rejection of claim 16 as being indefinite is moot.

Applicant respectfully submits that claim 16, as amended, is in full compliance with the requirements of 35 U.S.C. § 112, second paragraph, and requests that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

Claim Rejections - 35 U.S.C. § 103

The Examiner rejected claims 15, 16, 19 and 20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,929,231 (Pawlikowski) in view of European Patent No. 0148426 (Pharma Gummi). The Examiner acknowledges that Pawlikowski fails to disclose a base body being made substantially from an elastomer, being made in one piece or comprising a receiving cavity. Further, the Examiner admits that Pawlikowski fails to disclose a piston section being enclosed in a cap-shaped inert film where the film comprises a fluorinated polymer film. The Examiner relies upon Pharma Gummi to teach these features that Pawlikowski lacks and asserts that it would have been obvious to combine Pawlikowski and Pharma Gummi to create the piston stopper disclosed in the present application. The rejection of amended claim 15, and claims 16, 19 and 20 depending therefrom, is respectfully traversed.

Referring to Figs. 1-3, Pawlikowski, unlike Pharma Gummi, discloses a non-reusable hypodermic syringe 10 having a body 12 and a needle 14 extending from a front end 16 of the

body 12. An inwardly facing circumferential groove 36 is provided adjacent the front end 16 of the body 12. The groove 36 has a plane surface 38 perpendicular to the axis of the body 12 and a frusto-conical surface 40 which makes an acute angle with the surface 38. Further, the syringe 10 includes a plunger assembly 22 having a rod member 24 that extends from a rear end 18 of the body 12 and has at its rearward end a thumb-engaging enlargement 26. The front end of the rod member 24 has an integral head portion 28 that telescopingly fits within the body 12. The head portion 28 has an outwardly facing circumferential groove 30 and an O-ring 32 located therein that protrudes outwardly from the groove 30 and slidably engages the inner wall of body 12. A non-inert cap 34, which is deflectable to a frusto-conical shape when it engages the front end 16 of the body 12 (col. 2, lns. 41-43), is affixed to the head portion 28.

In operation, as the rod member 24 is pushed toward the front end 16 of the body 12, "the administrator of the injection will sense a change in the action of syringe 10, due to deformation of deformable cap 34 and will know that he or she must go a little further in order to cause O-ring 32 to snap into groove 36, thus to inject all of the required medication and achieve the desired locking and non-reusability of syringe 10" (col. 2, lns. 60-66).

Referring to Fig. 18, Pharma Gummi discloses a piston 33 for use in a pharmaceutical syringe. The piston 33 is comprised of three radially protruding sealing bulges 34, 35, 36. The first sealing bulge 34 is sheathed with a relatively hard, fluorinated polymer film 8, or a chemically inert film (pg. 9, lns. 5-7), which is undetachably connected to the rubber-elastic material of the piston 33 (col. 28, lns 6-10). The syringe disclosed by Pharma Gummi is reusable and is not designed to be discarded after one use.

Claim 15 of the present application is directed to a pharmaceutical piston stopper and recites, *inter alia*, as follows:

> *a piston section (8) enclosed in a cap-shaped inert film (9'), the piston section in a working position facing contents of a syringe or carpule cylinder (1), an outer circumference of the piston section with its inert film (9') abutting against the syringe or carpule cylinder (1), the piston stopper (2) having an uncoated sealing section (10) adjacent to the piston section (8), the uncoated sealing section and an edge region of the inert film (9') flatly abutting in the working position against the syringe or carpule cylinder (1), . . . and wherein the sealing section (10) has on its outer circumference an annular continuous sealing zone (13) directly adjacent to and directly adjoining the edge region of the inert film (9') enveloping the*

> *piston section (8) and abutting against an inside wall of the syringe or carpule cylinder (1), said annular continuous sealing zone (13) being aligned with a surface of the edge region of the inert film (9') or projecting slightly radially beyond the surface, so that in the working the piston stopper (2) abuts with the sealing section (13) fully against the syringe or carpule cylinder (1)*

Applicant respectfully submits that Pawlikowski and Pharma Gummi would not be combined by one having ordinary skill in the art in the manner proffered by the Examiner. Specifically, Pawlikowski discloses a cheap, disposable, one-use syringe 10. The syringe 10 is only designed to be used once because after the deflectable cap 34 deforms within the conical surface 40 and the O-ring 32 snaps into the groove 36, the rod member 24 is prevented from being removed from the body 12 without destroying the syringe 10. Enclosing the deflectable cap 34 in a relatively hard, inert film, as suggested by the Examiner, would prevent the cap 34 from deforming within the conical surface 40 and ultimately prevent the O-ring 32 from reaching and snapping into the groove 36. Further, to conserve money, non-reusable syringe 10 of Pawlikowski is made of inexpensive components (col. 1, lns. 20-23). Thus, the deflectable cap 34 is not intended to be enclosed in an inert cap that would increase the production cost of a syringe that will be discarded after one use.

It is respectfully submitted that Pawlikowski teaches away from enclosing and enveloping the piston section in an inert film, as is recited in the present application. Pawlikowski explicitly states that "typical prior art hypodermic syringes are physically reusable" and as such "this is highly undesirable" (col. 1, lns. 9-14). Since the Pharma Gummi patent was filed several years before the Pawlikowski patent, the Pharma Gummi syringe is the type of "prior art hypodermic syringe" that is explicitly disparaged by the Pawlikowski. Consequently, any attempt to modify Pawlikowski to include features of the physically reusable syringe of Pharma Gummi would clearly be contrary to the intent of Pawlikowski and improper.

Applicant respectfully submits that the two references would not be combined by one of ordinary skill in the art because there is no motivation for the combination. Specifically, Applicant respectfully submits that there is no motivation for one having ordinary skill in the art to modify the deflectable cap 34 of Pawlikowski to include an inert film, as proposed by the Examiner. For example, the deformable cap 34 and non-reusable syringe 10 of Pawlikowski

teach away from enclosing and enveloping the piston section in an inert film, as is recited in the present application.

> [W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. KSR International Co. v. Teleflex Inc., 127 S. Ct. 1721, 1740 (2007).

If the deformable cap 34 of Pawlikowski were enclosed in an inert film, as taught by Pharma Gummi, the cap 34 would no longer be deformable and the intended result of Pawlikowski, namely deformation of the cap 34 to the point at which the O-ring 32 snaps into the groove 36 (col. 2, lns. 63-64) could not be achieved. Further, since the syringe 10 of Pawlikowski is disposable or non-reusable, it would not be economical to enclose the deformable cap 34 in an inert film that increases the cost of producing the syringe 10. Therefore, the present rejection is an impermissible combination. One of ordinary skill in the art would not modify Pawlikowski to include an inert film enclosing the deflectable cap 34, because doing such would render the Pawlikowski syringe 10 inoperable for its intended purpose and unnecessarily increase the cost of producing the syringe.

A rejection may not be construed from parts selected from the prior art according to a blueprint drawn by the inventor himself. Innerconnect Planning Corp. v. Feli, 227 U.S.P.Q. 543 (Fed. Cir. 1985). Where a selective combination is required to render an invention obvious, there must be some reason for the combination other than hindsight obtained from the invention itself. While it is permissible to consider a reference for all it teaches (both preferred and nonpreferred embodiments), the selection of elements must have a firm foundation in the teaching, suggestion and motivation, provided by the reference when weighed as a whole. See Kalman v. Kimberly–Clarke Corp., 218 U.S.P.Q. 781, 791 (Fed. Cir. 1983).

It is well settled that patentability is not precluded just because all of the claimed elements of the invention are disclosed somewhere in the prior art.

> [A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

> KSR International Co. v. Teleflex Inc., 127 S. Ct. 1721, 1741 (2007). [Emphasis added].

It is respectfully submitted that in making the present rejection, the Examiner has employed impermissible hindsight in combining Pawlikowski and Pharma Gummi and concluding that it would have been obvious to enclose the deformable cap 34 of Pawlikowski with the inert film as taught by Pharma Gummi. This claimed feature is one aspect of the present application that sets it apart from the prior art. Moreover, the Examiner has ignored the negative teaching of Pawlikowski.

In the present application, the piston stopper 2 has a piston section 8 is enclosed in an inert film 9', an uncoated sealing section 10 located adjacent to the piston section 8, and an annular continuous sealing zone 13 on the outer circumference of the sealing section 10 that is directly adjacent and directly adjoining an edge region of the inert film 9' to provide a tight seal, especially from the side away from the liquid near the sealing zone 13 which prevents, for example, microbial or other contaminations from the outside from entering the syringe 10 from the backside. Further, the claimed structure of the present application minimizes the possibility that liquid in the syringe will contact the non-inert material, or the sealing section 10, and minimizes the possibility of liquid loss out the backside of the syringe.

Based upon each of the above, Applicant respectfully submits that amended claim 15, and claims 16, 19 and 20 depending therefrom, are patentable over Pawlikowski and Pharma Gummi and request that the rejection under 35 U.S.C. § 103(a) be withdrawn..

The Examiner also rejected claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Pawlikowski and Pharma Gummi, and further in view of U.S. Patent No. 2,895,773 (McConnaughey). The McConnaughey patent was cited because it discloses a piston cap having an internal thread to connect with a thread of the displacement transferring element. The McConnaughey patent does not disclose or suggest a piston stopper having a piston section enclosed in an inert film, an uncoated sealing section located adjacent to the piston section, and an annular continuous sealing zone on the outer circumference of the sealing section that is directly adjacent and directly adjoining an edge region of the inert film, as is recited in amended independent claim 15 of the present application. Applicant respectfully submits that claims 17 and 18, which are dependent upon claim 15, are patentable over Pawlikowski and Pharma

Gummi and further in view of McConnaughey for at least the same reasons discussed above for claim 15. Accordingly, Applicant respectfully submits that claims 17 and 18 are patentable over all of the references currently of record in the application.

For all the reasons above, Applicants respectfully submit that amended claim 15, and claims 16-20 depending therefrom, are patentable over all of the prior art of record and request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the foregoing Amendment and remarks, Applicant respectfully submits that the present application, including claims 15-20, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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(Date)

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